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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,600

08/08/2005

Nicolas Aurio

N-32529A

7126

1095

7590

03/26/2007

NOVARTIS

CORPORATE INTELLECTUAL PROPERTY

ONE HEALTH PLAZA 104/3

EAST HANOVER, NJ 07936-1080

EXAMINER

KOSAR, AARON J

ART UNIT

PAPER NUMBER

1609

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

03/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/516,600

Applicant(s)

AURIO ET AL.

Examiner

Aaron J. Kosar

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/08/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 19-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

2. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 19-21, is drawn to methods of making compositions using protein and fiber.

Group II, claim(s) 29, 38,41,44,47 are drawn to methods of making compositions using protein-fiber compositions

Group III, claim(s) 22-28,30-37,39-40,42-43,45-46 are drawn to protein-fiber compositions.

Group IV, claim(s) 48,50-51 are drawn to methods of using protein-fiber compositions.

3. The *inventions* listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The groups read upon the combination of a protein and fiber; however, the method of making and using and compositions comprising protein and fiber have been previously reported in the prior art of BELL, *et al.* (USPAT# 6210686). Bell teaches methods of making and using a cholesterol level effecting composition (column 3, lines 50-62) that comprises fibers (column 1, lines 44-58; column 3, lines 50-53) and protein (column 5, lines 34-41); therefore, with regards to the invention groups, unity of invention is lacking.

Election of Species

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Applicant elects claims group I, II, III, or IV above, Applicant must also elect species from each of the following species groups:

- A. fiber is generic to the species: *konjac gum, locust bean gum, tare bean gum, gum tragacanth, karaya gum, xanthan gum, arable gum, arabic gum, guar gum, gellan gum, pectin, β -glucan, mucilage, and carrageenan*. The species are structurally distinct, one from another, such that they, and the compositions which they comprise, would be expected to function differently, particularly *in vivo*. Additionally, the search for one species would not necessarily lead to the discovery of another, and thus would pose an undue burden to search the species together; therefore, Applicant is required to select a *single* species for initial prosecution of the claims.
- B. protein is generic to the species : *wheat protein, egg protein, collagen, whey protein, casein, soy protein, pea protein, muscle protein, gluten, fibrillar protein, silk protein, and hydrolysates thereof*. For the sake of compact prosecution , Examiner is interpreting the species “5 hydrolysates” (claim 19) as a typographical error of the originally disclosed “hydrolysates”. The species are structurally distinct, one from another, such that they, and the compositions which they comprise, would be expected to function differently, particularly *in vivo*. Additionally, the search for one species would not necessarily lead

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to the discovery of another, and thus would pose an undue burden to search the species together; therefore, Applicant is required to select a *single* species for initial prosecution of the claims.

If Applicant elects claims group II, III, or IV above, Applicant must also elect species from the following species group:

C. *metabolic syndrome, diabetes and lowering blood cholesterol* are distinct species. The fiber-protein combinations required to treat these distinct conditions would further comprise distinct drugs, different targets, and different modes of action. The conditions are mutually exclusive and a search of one condition would not necessarily lead to the discovery of the other conditions; therefore, Applicant is required to select a *single* species for initial prosecution of the claims.

5. The claims are deemed to correspond to the species listed above in the following manner:
 - a. Species groups A and B are claimed by claims 19-51.
 - b. Species group C is claimed by claims 29-51.

6. The following claim(s) are generic: Claim 19.

7. The *species* listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The groups read upon the combination of a protein and fiber; however, the method of using and compositions comprising protein and fiber have been previously reported in the prior art of Bell, *et al.* (USPAT# 6210686); therefore, unity of invention is lacking among the species.

6. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

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the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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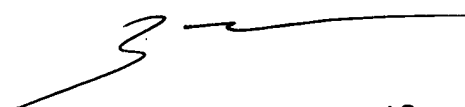
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on (571) 272-0235. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system: Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Kosar
Patent Examiner



ZACHARIAH LUCAS
PATENT EXAMINER